Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of siponimod 2mg tab manufactured by Zistdaru Danesh company versus originator brand in healthy volunteers in fasting condition

Protocol summary

Study aim
Bioequivalence Study of siponimod 2 mg (Relapzent) tab manufactured by Zistdaru Danesh company versus originator brand (Mayzent) manufactured by Novartis company

Design
Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct
The study is a single-blinded, crossover, and fasting study involving two series of healthy volunteers. The study will be done in two periods (96h). The interval between these two periods is 3 weeks. In the first round of the study, the candidates are divided into two groups, and the first group receives a test tablet and the second group receives a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. This test is performed in Radin laboratory in Tabriz.

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health (Liver, Heart, and Kidney), Body Mass Index of 18-28, Informed consent, Age of 18-55 years old. Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcohol and drug addiction, History of allergy to Siponimod

Intervention groups
Intervention group 1: Mayzent 2mg tab manufactured by Novartis as a reference. Intervention group 2: Relapzent 2mg tab manufactured by Zistdaru Danesh as a test

Main outcome variables
Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200623047902N47**
Registration date: **2026-01-27, 1404/11/07**
Registration timing: **prospective**

Last update: **2026-01-27, 1404/11/07**
Update count: **0**

Registration date
2026-01-27, 1404/11/07

Registrant information

Name
Elham Ghasemian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6696 5196

Email address
ghasemian@zistdaru.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-19, 1404/11/30

Expected recruitment end date
2027-02-19, 1405/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of siponimod 2mg tab manufactured by Zistdaru Danesh company versus originator brand in healthy volunteers in fasting condition

Public title
Bioequivalence study of siponimod 2mg tab

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index 18-28 Informed consent Age of 18-65 years old

Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to siponimod

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. Each number is written on plastic ball and poured into a container and mixed. The balls are then taken out randomly from the container. The odd numbers are considered as first sequence: Zistdaru Danesh's medicine and the pair numbers are considered as second sequence: originator brand recipient. The volunteers don't have any information about taking the test drug or brand drug

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded clinical trial (volunteers). Zistdaru Danesh's Siponimod and Originator brand's tablets are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences

Street address
Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2026-01-05, 1404/10/15

Ethics committee reference number
IR.TBZMED.REC.1404.738

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug concentration in plasma

Timepoint
Before and 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 7, 8, 10, 12, 24, 48, and 96 hours after drug administration

Method of measurement
Liquid chromatography-MASS-MASS (LC- Mas/Mas)

Secondary outcomes

1

Description
Time to reach maximum drug concentration in plasma

Timepoint
After intervention

Method of measurement
The time to reach the maximum drug concentration is recorded.

2

Description
Extent of drug absorption

Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group 1: single dose, one oral tab Mayzent 2 mg manufactured by Novartis as a reference product. after the washout period, the volunteers receive Relapzent 2 mg tab manufactured by Zistdaru Danesh Co.
Category
Treatment - Drugs

2

Description
Intervention group 2: single dose, one oral tab Relapzent 2mg manufactured by Zistdaru Danesh company as a test product. after the washout period, the volunteers receive Mayzent 2mg tab manufactured by Novartis Co.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Bahram Ataee
Street address
No.22, first floor, Azadi alley, Moalem st., Abureihan St.
City
Tabriz
Province
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Postal code
5154995671
Phone
+98 914 311 5717
Email
ghasemian_elham@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zistdaru danesh Co.
Full name of responsible person
Hooshmand Ilka
Street address
No.404, 4th floor, Rose mall complex, kharazi highway
City
Tehran
Province
Tehran
Postal code
1559836438
Phone
+98 21 4231 8100
Email
ilka@Zistdaru.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zistdaru danesh Co.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Radin Laboratory
Full name of responsible person
Elham Ghasemian
Position
Investigator of Bioequivalence study
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No.22, first floor, Azadi Alley, Moalem Street., Abureihan Street
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+98 914 313 5843
Email
ghasemian_elham@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Radin laboratory

Full name of responsible person
Elham Ghasemian

Position
Investigator of bioequivalence study

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Radin Laboratory

Full name of responsible person
Elham Ghasemian

Position
Investigator of Bioequivalence study

Latest degree
Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
These data are as secure between researchers and related industries.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available